ACKNOWLEDGEMENT TO AMENDMENT, RESPONSE TO THE RESTRICTION REQUIREMENT AND THE STATUS OF THE CLAIMS

The amendment and response to the restriction requirement filed 01/29/08 are acknowledged, entered and considered. In view of Applicant's request claims 73 and 98-102 have been amended and claim 103 has been added. Claims 73-103 are now pending in the application. Applicant's response with respect to the restriction requirement is noted. However, upon further consideration the restriction requirement of the previous Office action has been **vacated**. A new supplemental restriction is set forth below.

SUPPLEMENTAL ELECTION/RESTRICTION

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 73, 89-81 and 89, drawn to a method of treating infertility in a female mammal comprising administering a pharmaceutical agent comprising a gonadotrophin releasing hormone (GnRH) agonist which supports the luteal phase.

Group II, claims(s) 73-76, 85-88, 96 and 97, drawn to a method of treating infertility in a female mammal comprising administering a pharmaceutical agent comprising a GnRH

agonist, wherein the additional agent triggering final follicular maturation and ovulation is GnRH agonist administered to support the luteal phase.

Group III, claim(s) 73-75, 77, 85-88, 90-92, 94 and 95, drawn to a method of treating infertility in a female mammal comprising administering a pharmaceutical agent comprising a GnRH agonist, wherein stimulation of follicular growth and induction of final follicular maturation and ovulation is effected by the administration of at least one additional agent.

Group IV, claims(s) 73, 74, 85-88 and 93, drawn to a method of treating infertility in a female mammal comprising administering a pharmaceutical agent comprising a GnRH agonist, wherein the stimulation effected by the administration of the additional agent followed, before ovulation, by an oocyte retrieval procedure, wherein at least one oocyte is obtained.

Group V, claim(s) 73 and 82, drawn to a method of treating infertility in a female mammal comprising administering a pharmaceutical agent comprising a GnRH agonist, wherein the pharmaceutical agent which supports the luteal phase is administered in combination with another luteal support agent.

Group VI, claim(s) 73, 83 and 84, drawn to a method of treating infertility in a female mammal comprising administering a pharmaceutical agent comprising a GnRH agonist,

wherein the pharmaceutical agent which supports the luteal phase is administered in combination with a cytokine involved in embryo implantation mechanism.
Group VII, claim(s) 98-101, drawn to a method of treating infertility in a female mammal comprising administering a pharmaceutical agent which comprises a GnRH agonist comprising buserelin.

Group VIII, claim(s) 102 and 103, drawn to a kit for the treatment of infertility in a female mammal comprising a pharmaceutical agent comprising a GnRH agonist and packaging.

The inventions listed as Groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Groups I-VIII do not have common technical features that are inventive. That what is common is known, and if known is not special. For example, as acknowledged on page 9, lines 26-29 in the instant disclosure and as shown in the reference of Schmidt-Sarosi et al., Journal of Assisted Reproduction and Genetics, Vol. 12, No. 3, pages 167-174, 1995 (Provided by Applicant on IDS filed 08/22/05 under item C4) clearly discloses a method of treating infertility in a female by administering a pharmaceutical agent comprising GnRH agonist, nafarelin, in initiating ovulation and supporting the luteal phase (See e.g., abstract page 168 and discussion). Thus, the reference discloses what is common and known in the art the administration of GnRH agonist to treat infertility in female.

Therefore, the methods of Groups I-VII using the same known compound (i.e., GnRH agonist) as recited above do not correspond to the same technical features and are not connected in design, operation or effect because they differ in method steps, parameters and reagents used, and as such, the methods as grouped are independent and distinct, each from the other because they represent different technical features and different inventive endeavors. Hence, the compounds used in different methods have different structures, functions and different effects. Thus, the Groups require different patent and literature search and as such Groups I-VII do not share the same technical features, the inventions do not relate to the same inventive concept.

The inventions listed as Groups I-VII and VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The methods as claimed in Groups I-VII can be practiced by another different apparatus or by hand or the apparatus (the kit) as claimed can be used to practice anther and materially different processes. (MPEP § 806.05(e)). The methods of Groups I-VII can be practiced by another materially different apparatus such as the use or employment of implant, or inhalation or transdermally or manually by using a syringe for injection or other surgical means. There is no Unity of Invention between the methods of administration of Groups I-VII to treat infertility by intra-nasal, oral, sub-cutaneous, intramuscular, vaginal, rectal, transdermal and pulmonary route of administration and the kit formulation of Group VIII intended for the treatment of infertility. Thus, the

processes as recited above don not correspond to the same technical features and are not connected in design, operation or effect because they differ in method steps, parameters and reagents used, and as such, the methods as grouped are independent and distinct, each from the other because they represent different technical features and different inventive endeavors. Therefore, Groups I-VII and VIII do not share the same technical features, the inventions do not relate to the same inventive concept.

ELECTION OF SPECIES

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Species I is drawn to a GnRH agonist listed in claim 78.

If Applicant elects a synthetic peptide agonist of GnRH from Species I, Applicant must further elect the synthetic peptides listed in claim 79. If busereline elected as a synthetic peptide claims 80, 96 and 97 will be examined along the elected busereline.

Species II is drawn to pharmaceutical agents listed in claim 82.

Species III is drawn to cytokines listed in claim 84 and includes claim 83.

Species IV is drawn to additional agent stimulating follicular growth listed in claim 90.

If Applicant elects selective estrogen receptors modulators (SERM) from Species IV listed in claim 90, Applicant must further elect the SERM listed in claim 91. Similarly,

if Applicant elects aromatases inhibitors from Species IV listed in claim 90, Applicant must further elect the aromatase inhibitors listed in claim 92.

Species V is drawn to additional agent triggering final follicular maturation and ovulation listed in claim 93.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Species I-V are related as independent injectable pharmaceutical formulations comprising GnRH agonist containing different physiologically active proteins as active ingredients in which Species I-V are different formulations wherein the physiological active proteins in Species I is GnRH agonist, Species II is pharmaceutical agent, Species III is cytokine agent, Species IV is additional agent stimulating follicular growth, and Species V is additional agent triggering final follicular maturation and ovulation.

The following claim(s) are generic: claims 73-77, 81, 85-89 and 95.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Species I-V do not correspond to the same technical feature and are not connected in design, operation or effect because they differ in structure and formulation, and as such, the physiological active proteins as grouped are different from each other because they represent different technical features and different inventive endeavors. Hence, the physiological active protein formulations have different structures, functions and different effects. Thus, the species require different patent and literature search and a reference teaching the physiological active protein of GnRH agonist (Species I) will not teach the physiological active protein of pharmaceutical agents (Species II) or cytokines (Species III) or stimulating follicular growth agent (Species IV) or triggering final follicular maturation and ovulation agent (Species V) and *vice versa*. Therefore, Species I-V do not share the same technical features, the inventions do not relate to a single inventive concept.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

CONCLUSION AND FUTURE CORRESPONDANCE

Claims 73-103 are subject to restriction and/or species election requirement.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ABDEL A. MOHAMED whose telephone number is (571)272-0955. The examiner can normally be reached on First Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Mohamed/A. A. M./
Examiner, Art Unit 1654

/Jon P Weber/
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